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To: FDAockets@OC.FDA.gov/docketnumber78N0038

From: Ramon M. Fusaro MD, PhD

Professor of Preventive Medicine and Dermatology

Dept. of Preventive Medicine

Criss III 2500 California Plaza

Omaha NE 68178-0403 USA

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Re: Sunscreen labelling: Docket number 78N0038

Mislabelling of topical dihydroxyacetone (DHA) as having no UV photoprotective properties even though when it is applied overnight to the skin chemically changes the optical transmission properties of skin. In the FDA consumer reprint --- Seven Steps to Safer Sunning by Paula Kurtzweil on page 5 of the 7 page document, the following statement is made " The only color additive approved for extenders is dihydroxyacetone. Although they give skin a golden color, these products do not offer sunscreen protection." Such statements are untrue! This false statement of no photoprotective quality will result in two major areas of difficulty for physicians and patients. The first will be that the patient who receives topical DHA for its photoprotective quality will question the physician about the correctness of his therapy and cause mistrust in the patient doctor relationship and confusion in the understanding of the rational of its use in the patient's disorder. Secondly, it will lead to the denial of economic authorization of medical use of DHA by members of HMOs who have such cutaneous disorders as polymorphic light eruption. Estimates of photosensitivity in the white population have been as high as 10% of the population.

Experimental and clinical evidence show that the skin that has been treated with 3% DHA topical solution over night has an SPF of at least 3 in the UVB region of sunlight and a Photoprotective factor of 10 in the UVA region when treated with a 15% topical solution of DHA (references 1-10).

The advantages of the UVB protection are the DHA Induced Skin Pigment (DISP) is that it remains in the skin until it is desquamated off in the ensuing weeks and its can't not be removed by perspiration, swimming or soap and water. Thus, it provides temporary UVB protection when the regular sunscreen has been lost and allows protection for the patient until he or she can renew a new application of regular UVB sunscreens.

The DISP protection gives at least a photoprotective factor of 10 in the UVA region of ultraviolet and blue end of the visible spectrum. This photoprotection covers almost all forms of photosensitivity and the carcinogenic effect of UVA in melanoma enhancement.

References:

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C O V E R

FAX

S H E E T

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Subject: Sunscreen labeling of Dihydroxyacetone

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Pages: 3, including this cover sheet.

COMMENTS:

Enclosed comments for Regulation of Sunscreen Labeling,
specifically dihydroxyacetone sunless Tanning agent.

From the desk of...
Dr. Ramon M. TalamoUNMC - Dermatology
984360 Nebraska Medical Center
Omaha, NE 68198-4360(402) 559-4399
Fax: (402) 559-4104